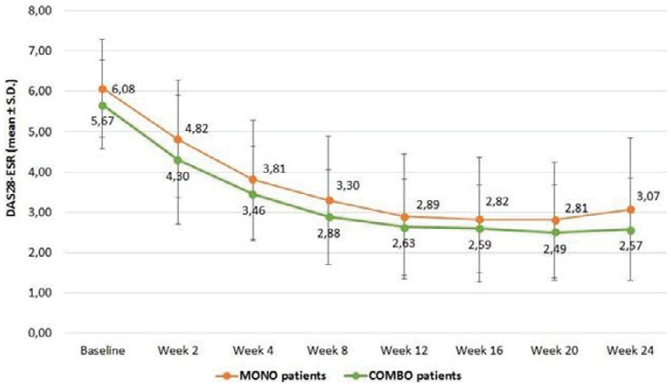
Results: The baseline characteristics of the 139 included patients were: mean age 57.3 years (±13.8), 74.1% female, mean RA disease duration 10.8 years (±9.2), immunopositivity 85.5%, structural joint damage 65.6%, mean DAS28 5.8 (±1.1). 52.5% of patients were bDMARD-IR. TCZ-SC was initiated in mono TCZ in 30.9% of pts and in combo in 69.1% (79.1% MTX). Oral CCS were used by 56.8% of pts (mean 7.4 mg/d/eq.pred.±2.7). In comparison with combo pts, the mono pts were older (58.7 vs 56.7 years), with a higher mean DAS28 (6.1 vs 5.7), a longer disease duration (11.5 vs 10.6 years), and a higher CCS mean dose (8.3 vs 6.9 mg/d/eq.pred.). At W24, the mean DAS28 score variation vs baseline was -3.1 overall ($p<0.0001$); -3.0 in mono TCZ vs -3.1 in combo TCZ ($p=0.76$) (Fig.). The proportion of pts who achieved DAS28 remission was 51.1% (41.9% in mono vs 55.2% in combo ($p=0.14$)). CDAI remission, which does not include acute phase reactants, was achieved in 17% pts, 16% in mono vs 17% in combo ($p=0.95$). At W24, 27.9% of pts receiving >5 mg CCS at baseline decreased the daily dose ≤5 mg/d/eq.pred. (30.1% in mono TCZ and 26.7% in combo). Out of the 23 pts (16.5%) who withdrew, 13.0% did so for lack of efficacy and 52.1% for safety reasons; one death occurred following a septic shock after surgery for gastric volvulus, not related to TCZ. At W24 95.7% of patients had experienced at least one adverse event (AE) and 10.1% at least one serious AE with similar rates between groups.



Conclusions: TCZ-SC demonstrated at 6 months comparable efficacy, safety and steroid sparing results in mono- and combo therapy consistent with the known profile of TCZ-IV.

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AB0396 TOCILIZUMAB I.V. EFFECTIVENESS IN RA PATIENTS IS INDEPENDENT OF SMOKING STATUS

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Background: Cigarette smoking is considered an established risk factor for the development of rheumatoid arthritis (RA) and for poor response in RA patients to treatment with conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) and with anti-tumor necrosis factor (anti-TNF) agents [1,2].

Objectives: This interim analysis of the German non-interventional study ICHIBAN (NCT01194401) assessed the effectiveness and safety of intravenously administered Tocilizumab (TCZ i.v.) with respect to patients' smoking status (smoker, ex-smoker, non-smoker).

Methods: Since 2010 the ICHIBAN study collects clinical data of the routine use of TCZ i.v. in RA patients. The observation period for each patient is up to two years. At the due date of the current interim analysis (Dec 10, 2015) 2999 patients were enrolled. 902 patients have completed the maximal 104 weeks observation period (Group W104). Patients were subgrouped according to their smoking status at baseline (BL).

Results: At BL the subgroups showed the following distribution: smokers 19.0%, non-smokers 52.5%, and ex-smokers 17.0%. The mean TCZ i.v. treatment duration was 1.7, 1.8, and 1.6 years, respectively, for the three groups.

In comparison to non-smokers and ex-smokers, smokers comprised a higher percentage of male patients, were younger, and showed shorter disease duration. Smokers showed slightly lower overall comorbidity rates, while COPD was observed almost three times more among smokers (3.5%) and ex-smokers (3.9%) than in non-smokers (1.3%). Concomitant use of csDMARDs and glucocorticoids (GC) was more frequent among smokers.

DAS28-ESR disease activity at BL was similar between the 3 subgroups. After 2 years TCZ i.v. therapy, disease activity was comparably decreased in all 3 groups. The mean reduction from BL in DAS28-ESR was 2.6 (smokers), 2.8 (non-smokers), and 2.5 (ex-smokers). At last visit, DAS28-ESR remission (<2.6) was reached by 48.0%, 52.3%, and 51.6% of patients, respectively The similar effectiveness of TCZ i.v. was also shown by patient reported outcomes via visual analogue scales (VAS).

Regarding safety, smokers showed higher event rates of adverse events (AE), serious adverse events (SAE), infections, and serious infections [Tab. 1]

Table 1 Effectiveness and safety of TCZ i.v. in RA patients

		W104 (Total)	Smokers	Non-smokers	Ex-smokers
Baseline characteristics, % (n)		100.0 (902)	19.0 (171)*	52.5 (474)*	17.0 (153)*
Sex (male), % (n)		23.8 (215)	40.9 (70)	15.8 (75)	33.3 (51)
Age [years], mean ± SD		55.7 ± 12.4	51.8 ± 10.1	56.8 ± 13.6	56.6 ± 11.4
Duration of RA [years], median		8.0	6.0	8.0	8.0
Comedication, % (n)					
• DMARDs		42.6 (384)	49.7 (85)	41.4 (196)	37.9 (58)
• GC		61.5 (555)	68.4 (117)	59.7 (283)	56.2 (86)
Comorbidities, % (n)		72.5 (654)	68.4 (117)	72.4 (343)	78.4 (120)
Effectiveness					
DAS28-ESR					
• Week 0 (Baseline), mean ± SD		5.5 ± 1.1	5.5 ± 1.1	5.5 ± 1.1	5.3 ± 1.0
• Last visit under TCZ, mean ± SD		2.7 ± 1.5	2.9 ± 1.7	2.7 ± 1.5	2.8 ± 1.5
• Change from BL, mean ± SD		-2.7 ± 1.6	-2.6 ± 1.7	-2.8 ± 1.7	-2.5 ± 1.5
• Remission (< 2.6), % (n)		51.9 (468)	48.0 (82)	52.3 (248)	51.6 (79)
VAS [mm], median (Q1, Q3)					
• Exhaustion/Tiredness	(Baseline)	60.0 (36, 79)	62.0 (31, 80)	59.0 (40, 78)	55.0 (34, 75)
•	(Last visit)	37.0 (14, 60)	39.0 (13, 62)	35.0 (15, 60)	40.5 (12, 57)
• Intensity of pain	(Baseline)	65.0 (45, 79)	67.0 (42, 80)	63.0 (45, 77)	62.0 (46, 78)
•	(Last visit)	30.0 (13, 56)	32.0 (16, 58)	30.0 (11, 53)	38.5 (15, 60)
• Sleep disturbances	(Baseline)	50.0 (21, 74)	48.0 (15, 80)	45.0 (21, 72)	50.0 (25, 72)
•	(Last visit)	30.0 (10, 60)	27.0 (5, 57)	28.0 (10, 59)	35.0 (12, 62)
Safety (event rate per 100 patient years)					
Adverse events (AEs)		80.1	99.0	74.6	97.9
Serious adverse events (SAEs)		19.4	30.4	15.7	22.2
Infections (AEs) **		21.8	29.4	20.5	26.3
Infections (SAEs) **		2.9	5.2	2.0	2.4
Discontinuations due to AEs		2.9	3.5	2.2	5.7

SD: Standard deviation; VAS: Visual Analogue Scale; Q1, Q3 = 1st / 3rd quartile

* Please note, that for 104 patients (11.5%) the smoking status is unknown

** Infections: All AEs/SAEs with a MedDRA Preferred Term indicating an infection

Conclusions: TCZ i.v. treatment over two years resulted in improvements of all disease activity parameters. Contrary to csDMARDs and TNF-blockers, the results show that smokers benefit from TCZ i.v. to the same extent as non-smokers and ex-smokers. The similar effectiveness of TCZ i.v. was confirmed by distinctly improved patient reported outcomes (PROs) in all subgroups. On the other hand, smoking seems to coincide with a higher rate of adverse events and an increased risk of infections. However, due to differences in baseline characteristics between the subgroups, this has to be interpreted with caution.

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